

REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks and amendments herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-153 are pending, and claims 26-52 and 124-140 are presently under examination. Claims 26, 46 and 124 are amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, as originally presented and as herein presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. Amendments to the claims, as presented herein, are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification and in the claims as originally presented.

II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claim 46 was objected to due to a typographical error in the spelling of "myocyte." The amendments herein correct this error, such that the objection is moot. Consequently, reconsideration and withdrawal of the objection to the claims is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claims 26-52 and 128-140 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

Specifically, the language "repairing and/or generating and or regenerating" in claim 26 was rejected as allegedly unclear as to which aspect of generating or regenerating damaged myocardium would not fall under the guise of repairing. The amendments herein have removed the redundant language, such that the rejection is moot. It is respectfully submitted that this amendment does not change the scope of the claims, as repairing and regenerating myocardium

fall under the term “repairing”. This amendment merely removes the redundancies for the sake of clarity.

Additionally, claims 33 and 128 were rejected for reciting the limitation “the patient” without proper antecedent basis. Again, the amendments herein have rendered this rejection moot.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112 is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 26-52 and 124-140 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Isner et al. (WO 99/45775). The rejection is respectfully traversed. The cited document does not teach or suggest the instant invention.

The Office Action states that Isner et al. “disclose[s] a method for forming new blood vessels or preventing or reducing the severity of blood vessel damage associated with ischemia ...comprising administering ... an effective amount of a vascularization agent such as Stem cell factor ..., GM-CSF, VEGF and others.” Office Action at 5-6. However, the Office Action fails to appreciate that Isner et al. describes only neovascularization, not the repair of damaged myocardial tissue.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

The instant claims relate to methods of repairing recently damaged myocardium and/or myocardial cells comprising the administration of a cytokine to a patient in need thereof. Further, the specification teaches the delivery of the cytokine directly to damaged cardiac tissue resulting from ischemia.

In contrast, Isner et al. discusses neovascularization in general, with the only specific

examples being of neovascularization or angiogenesis occurring in the cornea micropocket assay and the hindlimb ischemia model. Isner demonstrated only that an increase in vascular growth occurred in these models. Isner does not teach or suggest that the administration of growth factors repairs the tissue that has been damaged by ischemia. Isner is concerned only with the blood vessels themselves, not the surrounding tissue damaged by the lack of oxygen. In fact, the Office Action states that Isner is related to “preventing or reducing the severity of blood vessel damage.” Office Action at 5.

The Examiner’s attention is respectfully directed towards page 16 of Isner, wherein it states that “[a]s described above and in the examples following, we have discovered means to promote angiogenesis and reendothelialize denuded blood vessels in mammals.” Isner continues, stating that such methods may be used “for enhancing angiogenesis in a selected patient having an ischemic tissue.” While the methods are directed at patients who have suffered ischemic tissue damage, Isner’s methods only provide stimulation of angiogenesis in order to retard further tissue damage.

The present invention provides for the actual repair of ischemic tissue, including myocardium. The processes of retarding further damage, and repairing that which has already occurred are significantly distanced from one another such that no extrapolation between the two may be made. Methods and/or compositions to repair such damaged tissue are not contemplated, taught, or suggested by Isner et al. Consequently, the rejection over Isner et al. must fail. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview, with supervisory review, is respectfully requested, prior to issuance of any paper other than a Notice of Allowance, and the Examiner is additionally respectfully requested to telephonically contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

By this paper, this application is in condition for allowance. Favorable reconsideration of the application, reconsideration and withdrawal of the rejections of and objections to the instant

application, and prompt issuance of the Notice of Allowance, or an early interview, with a view towards reaching agreement on allowance, are, therefore, all earnestly solicited.

Respectfully submitted,

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